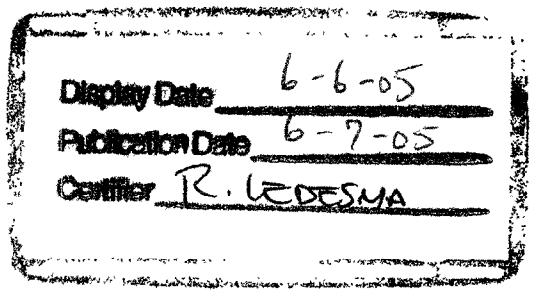
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0209]



PDM

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Contact Substances Notification System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information associated with the Food Contact Substances Notification System.

DATES: Submit written or electronic comments on the collection of information by [*insert date 60 days after publication in the* **Federal Register**].

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Food Contact Substances Notification System—21 CFR 170.101 and 170.106—(OMB Control Number 0910–0495)—Extension

Section 409(h) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(h)) establishes a premarket notification process for food contact substances. Section 409(h)(6) of the act defines a "food contact substance" as "any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food." Section 409(h)(3) of the act requires that the notification process be used for authorizing the marketing of food contact substances except where FDA determines that the submission and premarket review of a food additive petition (FAP) under section 409(b) of the act is necessary to provide adequate assurance of safety or where FDA and the manufacturer or supplier agree that an FAP should be submitted. Section 409(h)(1) of the act requires that a notification include information on the identity and the intended use of the food contact substance and the basis for the manufacturer's or supplier's determination that the food contact substance is safe under the intended conditions of use.

Sections 170.101 and 170.106 of FDA's regulations (21 CFR 170.101 and 170.106) require that a food contact notification (FCN) include FDA Form 3480 entitled "Notification for New Use of a Food Contact Substance" and that a notification for a food contact substance formulation include FDA Form 3479 entitled "Notification for a Food Contact Substance Formulation." These forms will serve to summarize pertinent information in the notification. FDA believes that these forms will facilitate both preparation and review of notifications because the forms will serve to organize information necessary to support the safety of the use of the food contact substance. The burden of filling out the appropriate form has been included in the burden estimate for the notification.

Description of Respondents: Manufacturers of food contact substances.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Form	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.106[2] (Category A)	5	FDA 3479	1	5	2	10
170.101 [3,7] (Category B)	5	FDA 3480	1	5	25	125
170.101 [4,7] (Category C)	5	FDA 3480	2	10	120	1,200
170.101 [5,7] (Category D)	33	FDA 3480	2	66	150	9,900
170.101 [6,7] (Category E)	30	FDA 3480	1	30	150	4,500
Total						15,735

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Notifications for food contact substance formulations and food contact articles. These notifications require the submission of FDA Form 3479 ("Notification for a Food Contact Substance Formulation") only.
[3] Duplicate notifications for uses of food contact substances.
[4] Notifications for uses that are the subject of exemptions under 21 CFR 170.39 and very simple food additive petitions.
[5] Notifications for uses that are the subject of moderately complex food additive petitions.
[6] Notifications for uses that are the subject of very complex food additive petitions.
[7] These notifications require the submission of FDA Form 3480.

These estimates are based on FDA's experience with the food contact substances notification system.

- Based on input from industry sources, FDA estimates that the agency will receive approximately five notifications annually for food contact substance formulations.

- FDA also has included five expected duplicate submissions in the second row of table 1 of this document. FDA expects that the burden for preparing these notifications primarily will consist of the manufacturer or supplier filling out FDA Form 3480, verifying that a previous notification is effective, and preparing necessary documentation.

- Based on the submissions received, FDA identified three other tiers of FCNs that represent escalating levels of burden required to collect information (the third, fourth and fifth rows of table 1 of this document).

• FDA estimated the median number of hours necessary for collecting information for each type of notification within each of the three tiers based on input from industry sources.

Dated: 5/31/05
May 31, 2005.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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